

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

In re BAYCOL PRODUCTS LITIGATION

MDL No. 1431  
(MJD/SRN)

This Document Relates to:

*United States of America ex rel. Laurie Simpson*  
*v. Bayer Healthcare d/b/a Bayer Healthcare Pharma, et al.* Case No. 08-5758

**DEFENDANTS' REPLY IN SUPPORT  
OF MOTION TO DISMISS**

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## INTRODUCTION

Laurie Simpson may call herself the “paradigmatic whistleblower” (Opp. at 1), but her claims “add nothing to the exposure of” an alleged fraud on the government. *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1511 (8th Cir. 1994). As Bayer demonstrated in its opening brief, Ms. Simpson cannot carry her burden of establishing this Court’s jurisdiction because her claims recycle allegations long a matter of public record and because her sworn testimony demonstrates that she is not an original source of those allegations.

Ms. Simpson makes three arguments in an attempt to evade her burden of demonstrating this Court’s jurisdiction under the False Claims Act. First, she asserts that the Court should ignore the jurisdictional evidence presented by Bayer and accept the allegations in her complaint as true. Memorandum of Law in Opposition to Defendants’ Motion to Dismiss, Docket Entry 29 (“Opp.”) at 7. On a Rule 12(b)(1) motion, however, the Court can and should consider the evidence necessary to determine whether it has jurisdiction. *See, e.g., Parsons v. United States Air Force*, No. 99-2985, 2000 WL 748097, at \*1 (8th Cir. June 12, 2000).

Second, Ms. Simpson contends that allegations made public years ago in the Baycol products liability litigation should be treated as “new key allegations of fraud” because they are now being made by a qui tam relator. Opp. at 13. This argument would write out of the False Claims Act the “public disclosure” limitation on jurisdiction (31 U.S.C. § 3730(e)(4)(A)), which bars lawsuits where the relator is taking advantage of information already in the public domain. *Rabushka*, 40 F.3d at 1511. As demonstrated

in Bayer's opening brief and below, the supposedly new allegations made by Ms. Simpson have been around for years. Accordingly, this Court can exercise jurisdiction only if Ms. Simpson can demonstrate that she is an original source of the specific matters alleged. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 460 (2007).

Third, Ms. Simpson contends that this Court should ignore her sworn testimony explicitly disavowing personal knowledge of the matters she now alleges in her complaint. Opp. at 23-28. She offers three rationalizations:

- She again argues that the Court must accept the allegations of her complaint as true under Rule 12(b)(6). Opp. at 8. But the issue here is subject matter jurisdiction, and this Court can and should consider evidence to determine whether it has jurisdiction. *Osborn v. United States*, 918 F.2d 724, 730 n.6 (8th Cir. 1990).
- She asserts that the Court should disregard her deposition – although she does not dispute the truth of her testimony – because she answered only the questions put to her by examining counsel. Opp. at 25. If that rationale allowed a witness to walk away from sworn testimony, no witness would be bound by evidence given under oath.
- Ultimately, Ms. Simpson accuses Bayer of mischaracterizing her sworn testimony. *Id.* This Court has her deposition transcript and can see for itself that Ms. Simpson repeatedly and explicitly testified to her lack of personal knowledge of the core matters alleged in her complaint. That testimony makes it impossible for her to demonstrate that this Court has jurisdiction over her False Claims Act claims.

Even if this Court had jurisdiction – and it does not – Ms. Simpson's claims should be dismissed because she has failed to plead fraud with particularity: she has not provided the specifics regarding the submission of even one ostensibly false claim and she has not properly alleged scienter. Ms. Simpson's response is that all her *other* allegations (the ones garnered from the public record) are so specific that they provide



circumstantial evidence of a false claim and scienter. Opp. at 19-22, 31. The Eighth Circuit, however, has rejected this view, holding that a qui tam plaintiff must provide “representative examples” of false claims “specifying the time, place, and content . . . and the identity of the actors.” *United States ex rel. Joshi v. St. Luke’s Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006). Because Ms. Simpson has not pled the who, what, when, where, and how of any allegedly fraudulent claim for government payment, her claims under the False Claims Act must be dismissed.

Turning to Ms. Simpson’s remaining claims, she does not dispute Bayer’s showing that she cannot assert a reverse false claim or a claim for conspiracy. *See* Memorandum of Law in Support of Defendants’ Motion to Dismiss, Docket Entry 27 (“Defs.’ Br.”) at 29. Nor does Ms. Simpson dispute Bayer’s showing that she cannot assert a claim under the Anti-Kickback Statute, because there is no private cause of action under that statute. *Id.* at 33. Instead, she now attempts to characterize her anti-kickback claim as arising under the False Claims Act. Opp. at 34. But an alleged violation of the Anti-Kickback Statute should not provide a basis for a False Claims Act claim. *See, e.g., United States ex rel. Thomas v. Bailey*, 2008 WL 4853630, at \*9 (E.D. Ark. Nov. 6, 2008). And even if it did, that claim would fail for lack of jurisdiction and failure to plead the claim with specificity. Ms. Simpson also does not dispute that her claims are time-barred for virtually all of the period Baycol was on the market. Opp. at 35. Finally, her state law claims fail for the same reasons as her federal law claims.

In sum, Ms. Simpson has failed to carry her burden of establishing this Court’s jurisdiction, pleading fraud with particularity or, more generally, demonstrating

that this suit is anything other than a “parasitical sui[t] in which the informer rendered no service to the government.” *United States ex rel. Minn. Ass’n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1041 (8th Cir. 2002). Her case therefore should be dismissed.

## ARGUMENT

### **I. SIMPSON’S COMPLAINT SHOULD BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT.**

#### **A. This Court Should Decide Now Whether Ms. Simpson Has Carried Her Burden of Establishing Jurisdiction Over Her Claims.**

As a preliminary matter, Ms. Simpson argues that, under Rule 12(b)(6), this Court must accept as true all of the allegations in her complaint. However, Bayer has moved to dismiss Ms. Simpson’s claims for lack of jurisdiction under the False Claims Act, 31 U.S.C. § 3730(E)(4)(A). A jurisdictional motion under the False Claims Act is treated like any other jurisdictional motion under Rule 12(b)(1). *See, e.g., United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 673 (8th Cir. 2003) (affirming dismissal of False Claims Act claims under Rule 12(b)(1) for lack of jurisdiction); *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 357 (4th Cir. 2009) (same); *United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr.*, No. 4:05-CV-00899, 2007 WL 2904111, at \*1 (E.D. Ark. Sept. 28, 2007) (dismissing False Claims Act claim under Rule 12(b)(1) for lack of subject matter jurisdiction).

Accordingly, before addressing the merits of this case, the Court must decide whether it has subject matter jurisdiction. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94 (1998) (“declining to endorse” the “practice – which [the

circuit court] characterize[d] as ‘assuming’ jurisdiction for the purpose of deciding the merits – [or] the ‘doctrine of hypothetical jurisdiction’” because, as “reflected in a long and venerable line of our cases,” “[w]ithout jurisdiction the court cannot proceed at all in any cause”); *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006).

Where, as here, the jurisdictional challenge concerns failure to meet the requirements in 31 U.S.C. § 3730(e)(4)(A), the court may consider matters outside the pleading.<sup>1</sup> *Osborn*, 918 F.2d at 730 n.6 (“In a factual attack . . . the court considers matters outside the pleadings”) (internal citations and quotations omitted); *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007) (“a Rule 12(b)(1) challenge to jurisdiction” is a “factual attack to jurisdiction” because “it concerns not an alleged pleading deficiency, but rather the actual failure of relator’s claims to comport with the jurisdictional prerequisites contained in 31 U.S.C. § 3730(e)(4)” and on which “it is permissible for a court to review evidence outside the pleadings”) (internal citations omitted); *Parsons*, 2000 WL 748097, at \*1 (on “defendant’s [Rule 12(b)(1)] jurisdictional challenge . . . the District Court was [] free to weigh evidence and determine the existence of its power to hear the case”).<sup>2</sup>

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<sup>1</sup> Rule 12(b)(1) jurisdictional attacks may be facial or factual. *Safe Air v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004); *Holt v. United States*, 46 F.3d 1000, 1002-03 (10th Cir. 1995). Facial attacks assert that the allegations of a complaint are insufficient on their face to invoke federal jurisdiction; factual attacks dispute the truth of the allegations used to invoke federal jurisdiction and thus *require* a court to look at the facts in order to determine whether it has jurisdiction to consider the case. *Holt*, 46 F.3d at 1003.

<sup>2</sup> See also *Jones v. Novastar Fin., Inc.*, No. 08-00490, 2009 WL 331553, at \*4 (W.D. Mo. Feb. 11, 2009) (“on factual challenges to subject matter jurisdiction, courts are free to ‘weigh evidence and satisfy [themselves] as to the existence of [their] power to hear

Relator bears the burden of establishing jurisdiction by “alleging facts essential to show jurisdiction under the [False Claims Act] as well as supporting those allegations with competent proof.” *United States ex rel. Pritsker v. Sodexo*, No. 03-6003, 2009 WL 579380, at \*6 (E.D. Pa., Mar. 6, 2009) (citing *United States ex rel. Grynberg v. Praxair, Inc.*, 389 F.3d 1038, 1048 (10th Cir. 2004); *Atkinson*, 473 F.3d at 514 (“the District Court . . . properly placed the burden of establishing jurisdiction on” the relator); *United States ex rel. Hafter, D.O. v. Spectrum Emergency Care, Inc.*, 190 F.3d 1156, 1160 n.5 (10th Cir. 1999) (where there is a factual attack on jurisdiction, relator “must present affidavits or other evidence sufficient to establish the court’s subject matter jurisdiction by a preponderance of the evidence”).

“[N]o presumptive truthfulness attaché[s] to [the relator’s] allegations,” and to establish jurisdiction, the relator must plead more than conclusory assertions. *Parsons*, 2000 WL 748097, at \*1; *Sodexo*, 2009 WL 579380, at \*14; *United States ex rel. Feldstein v. Organon, Inc.*, No. 07-cv-2690, 2009 WL 961267, at \*4 (D.N.J. Apr. 7, 2009); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 28 (1st Cir. 2009). To the contrary, in considering a factual challenge to jurisdiction, like this one, a court “may not presume the truthfulness of the complaint’s factual allegations.” *Holt*, 46 F.3d at 1003; *see also White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000).

Ms. Simpson nevertheless contends that the Court should ignore this well-established law – and accept the allegations of her complaint as true – because the

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the case”); *United States ex rel. Montgomery*, No. 4:05-cv-00899, 2007 WL 2904111, at \*3 (“the court is free to consider jurisdictional facts outside the pleadings in considering its subject matter jurisdiction”).

jurisdictional inquiry is intertwined with the merits. Opp. at 7. She claims such a result because some courts have converted Rule 12(b)(1) to Rule 12(b)(6) or 56 to resolve jurisdictional issues. *Id.* at 7-8. But that is beside the point, as Simpson's own cases demonstrate. For instance, in *Hafter*, the Court expressly noted that "[w]hether we consider Spectrum's motion as a motion to dismiss under Rule 12(b)(1) or a motion for summary judgment, Appellants' burden remains essentially the same – they must present affidavits or other evidence sufficient to establish the court's subject matter jurisdiction by a preponderance of the evidence," and thus not rely solely on the allegations of their complaint. 190 F.3d at 1160 n.5 (citing *Trentacosta v. Frontier Pac. Aircraft Indus., Inc.*, 813 F.2d 1553, 1559 (9th Cir. 1987)). And, in *Bryce v. Episcopal Church*, 121 F. Supp. 2d 1327, 1334 (D. Colo. 2000), the Court held that, in the context of a factual jurisdictional attack like this one, the Court "may not presume as true the allegations contained in the complaint," when it converted a 12(b)(1) motion to a Rule 56(c) motion.

In any event, here the jurisdictional question is not "intertwined" with the merits. The jurisdictional question is whether Ms. Simpson had direct and first hand knowledge of the allegations. The merits are whether Bayer made false claims by misrepresenting the safety and efficacy of Baycol. These are two different inquiries.

Ms. Simpson also seems to suggest that, simply because the case is brought under the False Claims Act, the Court cannot decide whether it has jurisdiction as a threshold matter. Opp. at 8. This is simply wrong. There are myriad cases arising under the False Claims Act in which the court followed the usual procedure of determining whether it had jurisdiction at the outset of the case, including two cited by Ms. Simpson –

*Hafter*, 190 F.3d 1156 (10th Cir. 1999), and *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg. Healthcare Sys.*, 274 F. Supp. 2d 824 (S.D. Tex. 2003). *See also, e.g., Rabushka*, 40 F.3d at 1513-14 (considering facts regarding jurisdiction on an appeal from the district court's grant of a motion to dismiss); *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 551 (10th Cir. 1992) (affirming dismissal of complaint for lack of jurisdiction based on evidence produced by defendant); *United States ex rel. Rille v. Accenture LLP*, No. 4:04-cv-985, 2009 WL 941036, at \*1 (E.D. Ark. Apr. 3, 2009) (considering more than 70 exhibits on motion to dismiss regarding jurisdiction under False Claims Act); *United States ex rel. Her v. Regions Financial Corp.*, No. 06-2178, 2008 WL 2370942, at \*5 (W.D. Ark. June 3, 2008) (dismissing a claim under the False Claims Act for lack of jurisdiction); *Montgomery*, 2007 WL 2904111 (granting defendant's motion to dismiss for lack of jurisdiction). This Court should do the same: examine its subject matter jurisdiction now, on the evidentiary record presented by the parties, and dismiss relator's complaint.

**B. Ms. Simpson's Claims Are Based on Prior Public Disclosures.**

The False Claims Act bars jurisdiction after "essential elements comprising [the] fraudulent transaction have been publicly disclosed" unless the relator can show that she is an original source – which Simpson cannot do (*see infra* at Part I.C). *Rabushka*, 40 F.3d at 1514 (citing 31 U.S.C. 3730(e)(4)(A)). A complaint is "based upon" publicly revealed allegations if it is "'supported by' or 'substantially similar to' the disclosed allegations and transactions." *Atkinson*, 473 F.3d at 519 (quoting *United States ex rel. Mistick PBT v. Housing Auth. of City of Pittsburgh*, 186 F.3d 376, 385-88 (3d Cir.

1999)). As Bayer demonstrated in its Opening Brief, Ms. Simpson's Amended Complaint, Docket Entry 6 ("Am. Compl.") is based on well-worn allegations that Bayer concealed Baycol's risks and engaged in improper and unlawful marketing strategies – allegations that have been around for years. *See* Defs.' Br. at 11-16.

Ms. Simpson contends that the allegations in her complaint were not publicly disclosed within the meaning of the False Claims Act because the information previously available was not sufficient to support a fraud allegation. She then cites a series of ostensibly new allegations from her complaint, none of which is actually new. For instance:

**"New" allegation:** "In September 1998, Bayer Pharmaceutical CEO Dr. David Ebsworth, personally proposed and implemented the use of deceptive promotional material in conjunction with his direction that Bayer should aggressively market Baycol and 'push the legal limits.'" Opp. at 13; Am. Compl. ¶¶ 53-54.

**Already public:** This allegation should be very familiar to this Court. The PSC recited the allegation in this Court in 2003 during the hearing on class certification.<sup>3</sup> The allegation also was raised in 2003 in *Haltom*: "the then-president, Dr. Ebsworth, had . . . giv[en] his rules to 'Stretch the data' and 'We don't know the legal boundaries until we hit it.'"<sup>4</sup>

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<sup>3</sup> *See In re Baycol Prods. Liability Litig.*, MDL No. 1431, Class Cert. Hrg., PSC's Opening Statement by Richard Arcenault at 13:5-20 (D. Minn., Feb. 6, 2003) (Ex. 6) ("What we have here were excerpts from minutes from the September 30, 1998 Baycol [b]rand review meeting and they spell it out. We need to stretch the data to the maximum. Other companies have developed an attitude of pushing marketing material aggressively, following the philosophy, we do not know where the legal boundary is until we hit it. One may not value this, but since it is the rule in the market, we as a company have to follow it. The area is greater than we treat it. We can pick the better study for the detail aid. It is the role of marketing to challenge regulatory systematically.").

<sup>4</sup> *Haltom v. Bayer*, No. 02-60165-4, Trial Tr., Plaintiff's Opening Statement (Ex. 2) at 19:6-11 (Neuces Cty, Ct., Tex., Feb. 20, 2003).

**“New” allegation:** “Bayer made the misleading promotional statement that the 0.8 mg dose of Baycol caused 84% of patients to reach the National Cholesterol Education Program’s goal.” Opp. at 14; Am. Compl. ¶¶ 89-90.

**Already public:** A third-party payer class action in this MDL alleged that Bayer represented “by advertising to doctors that Baycol was ‘more powerful’ and so effective that ‘84% of patients’ reached their cholesterol level goals, while burying the risks of Baycol in fine print.”<sup>5</sup>

**“New” allegation:** “Bayer ignored Ms. Simpson’s recommendation that the sales representatives be told explicitly of the full extent of the serious risks of starting patients on a .8 mg dose, instead downplaying the risks.” Opp. at 14; Am. Compl. ¶ 107.

**Already public:** Allegations that Bayer downplayed the higher risk of the .8 mg dosage have been made throughout this litigation.<sup>6</sup>

These are but a few examples. Exhibit 1 to this Reply<sup>7</sup> demonstrates that each of Ms. Simpson’s supposedly “new allegations” repeats claims previously made during the almost five years of Baycol litigation that preceded the filing of her complaint.

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<sup>5</sup> *Allied Servs. Div. Welfare Fund v. Bayer A.G.*, No.02-1255, Complaint (Ex. 10) ¶ 54 (D. Minn. June 10, 2002).

<sup>6</sup> *See, e.g., In re Bayer AG Sec. Litig.*, No. 03 C 1546, Complaint (Ex. B) ¶ 71 (S.D.N.Y., Jan. 14, 2005) (“Despite accumulating evidence that Baycol was unsafe, defendants pressed ahead with their plans and received FDA approval to market an 0.8 mg dose in July 2000. During this time, defendants continued to receive notice of adverse events associated with Baycol, both directly from doctors and from the FDA. These adverse events were more frequent with doses of 0.4 mg and higher.”); *id.* ¶ 90 (“At the time Bayer launched the 0.8 mg version of Baycol in the U.S., its own studies showed that starting a patient’s treatment at the high dose was very dangerous.”); *Allied Servs. Div. Welfare Fund*, No. 02-1255, Complaint (Ex. 10) ¶ 55 (D. Minn., June 10, 2002) (“instead of discussing the adverse reactions to Baycol at a 0.8 mg dose, Defendants lumped all the clinical studies together, including those from the initial new drug application for doses at 0.2 mg and below, and asserted that ‘in clinical trials with 5,000 patients, the most common adverse events, regardless of causality, were pharyngitis, rhinitis, headache, and sinusitis”).



At bottom, Ms. Simpson's claim is that these old allegations from the tort and securities cases became new when repeated by a relator in a qui tam complaint. Opp. at 12, 15, 16. But dressing up the same old allegations in a different cause of action does not make them new allegations. *See Costner v. URS Consultants, Inc.*, 153 F.3d 667, 674 (8th Cir. 1998) (observing that a False Claims Act claim may not be "simply a repackaging of prior claims"); *Minn. Ass'n*, 276 F.3d at 1047 (prior antitrust case contained essential elements of the qui tam action); *Ross v. United States*, No. 94-55559, 1994 WL 693167, at \*1 (9th Cir. Dec. 9, 1994) ("Although the actions purportedly assert new legal theories . . . they involve the same factual allegations . . . made in previous lawsuits."); *see also, Haynes v. Lemann*, 921 F. Supp. 385, 390 (N.D. Miss. 1995) (rejecting claims that are "simply new dressings on old allegations").

The cases Ms. Simpson cites are not to the contrary. Ms. Simpson describes *United States ex rel. Her v. Regions Financial Corp* as "directly on point." Opp. at 15. That case held a False Claims Act relator was entitled to proceed against a bank for fraudulent losses on a guaranteed loan, notwithstanding earlier litigation in state court based on the same loan. But Ms. Simpson conveniently overlooks a critical fact: the earlier litigation involved an altogether different fraud (one related to the initial loan process and not an already secured loan). No. 06-2178, 2008 WL 2370942, at \*4 (W.D. Ark. June 3, 2008). Similarly, in *Rabushka*, the Eighth Circuit held certain publicly disclosed information did not trigger the False Claims Act's jurisdictional bar because it

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<sup>7</sup> Exhibits cited by letter were filed with the Memorandum in Support of Defendants' Motion to Dismiss (D.E. 27); those referred to by number are being filed concurrently with this Reply Brief.

exposed only innocuous details (transaction structure and the fact of bankruptcy), not a fraudulent transaction responsible for the bankruptcy. 40 F.3d at 1514. *See also United States ex rel Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 653 (D.C. Cir. 1994) (holding that public disclosure of pay vouchers and telephone records – insufficient alone to expose any fraud – could not bar jurisdiction under the False Claims Act).

In this case, however, the precise allegations on which Ms. Simpson bases her fraud claims have long been a part of the public record. The only thing new about her allegations is that they are now made in a qui tam complaint. Because the “essential elements” cited by Ms. Simpson in support of her False Claims Act claims have been publicly disclosed, Ms. Simpson must prove that she is an original source to establish this Court’s jurisdiction. And that she cannot do.

**C. Simpson Cannot Show that She Is an Original Source because, Under Oath, She Denied Knowledge of the Core Allegations of Her Complaint.**

Ms. Simpson cannot establish that she is an “original source” of the allegations in her complaint. She cannot demonstrate that she “has direct and independent knowledge of the information on which the allegations are based,” 31 U.S.C. § 3730(c)(4)(B), because she denied having such knowledge when she was deposed in this MDL. In response, Ms. Simpson asserts that the Court should ignore the sworn testimony cited by Bayer, Opp. at 23-28, and should instead accept at face value her current claim to be an original source, *id.* at 19-23. Ms. Simpson is wrong on both points.

**1. Ms. Simpson is bound by her testimony in this MDL.**

Ms. Simpson gives three reasons why the Court should ignore her sworn testimony, none of which withstands examination. *First*, she repeats her argument that the Court should accept the complaint as true under Rule 12(b)(6) and ignore other evidence. This argument is wrong for the reasons set forth in Part I.A.1.

Ms. Simpson asserts that she should be allowed to walk away from her deposition testimony because she was advised to answer questions narrowly, PSC counsel did not ask the right questions, and she feared retaliation by Bayer if she volunteered additional information. Opp. at 25-26; Declaration of Laurie Simpson, Docket Entry 30 (“Simpson Decl.”) ¶¶ 9 & 10.<sup>8</sup> Significantly, ***Ms. Simpson does not suggest that her testimony was false.*** Ms. Simpson cites no authority – and Bayer is aware of none – holding that a Court should ignore sworn testimony because the witness did not volunteer additional information or answer questions that she was not asked.

*Third*, Ms. Simpson asserts that Bayer has misrepresented her testimony. She says that, while she testified that she did not have *responsibility* for certain activities, such as communication to physicians and labeling, that does not mean she lacked *knowledge* about those activities. Opp. at 26; Simpson Decl. ¶ 4. To illustrate, Ms. Simpson asserts that she had knowledge that Bayer deliberately downplayed to physicians the contraindication in the Baycol label. *See* Opp. at 26; Am. Compl. ¶¶ 77-

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<sup>8</sup> Ms. Simpson also asserts that she lost her job because of her complaints about Bayer’s marketing practices. Opp. at 25. She neglects to mention that virtually all operations have been discontinued at the Connecticut facility where she worked and that there was a widespread reduction in work force at the time of her departure.

82; Simpson Decl. ¶¶ 7, 11-13. Based on her deposition testimony, this is not true.

During her deposition, PSC counsel repeatedly tried to elicit testimony that Bayer downplayed the contraindication, and Ms. Simpson consistently denied that assertion or testified that she did not have knowledge about the specific matter raised by counsel:<sup>9</sup>

Q. Were you aware that Bayer management wanted to put a positive spin on the contraindication and notifying doctors of it?

A. I was not aware of a positive spin being desired.

Simpson Dep. (Ex. A) at 260:19-25.

Q. Was there any changes made, prior to May of 2001, with regard to the labeling of the contraindication of Gemfibrozil and Baycol?

A. I don't know.

Q. So you know of no interventions designed to improve the awareness of Baycol and contraindication?

A. There were ongoing efforts to improve the communication of that information.

Q. Tell me what they were.

A. What they were, I am not familiar with it. I did not participate in that.

Q. So you have no knowledge of any interventions designed to improve awareness of Baycol and the contraindications with Gemfibrozil?

A. There was communications and meetings with the sales force to reiterate the contraindication and the importance of communicating the contraindication.

Beyond that, I really wasn't participating in it.

*Id.* at 338:14-339:13.

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<sup>9</sup> Objections to form have been omitted from these deposition excerpts.

Q. Did you set up any specific program with the opinion leaders to get out the news to other physicians that the combination therapy of Baycol and Gemfibrozil was contraindicated?

A. I wasn't participating in that, but I believe so.

Q. Okay. Well you believe so.

What information do you have that suggests that?

A. I know that we had advisory boards, where they communicated that, and it was part of – a medical presentation program would have included that information as well.

Q. Did you have any – did you participate in the preparation of any of that material?

A. No.

*Id.* at 352:8-25.

Q. Weren't you trying to get out to the doctors the idea that Gemfibrozil is a class effect and not related to Baycol?

\* \* \*

That's exactly what you told your sales force in the introduction of the .8. Right?

A. We told them that there was a contraindication with Gemfibrozil and Baycol and this should be communicated and that all statins had a risk of rhabdo when used in combination.

Q. Well, weren't you suggesting to the sales force that all statins should have a contraindication?

A. No.

*Id.* at 358:22-24, 360:19-361:6.

Plainly, Bayer has not misrepresented Ms. Simpson's testimony regarding marketing, labeling, and the contraindication. While Ms. Simpson may have had

“knowledge” concerning marketing and labeling relating to the contraindication, she did not have knowledge of the supposedly fraudulent wrongdoing now alleged in her complaint. Accordingly, Ms. Simpson cannot be an original source of allegations that Bayer downplayed the contraindication.

Similarly unavailing are Ms. Simpson’s attempts to cast herself as an original source of allegations that Bayer misrepresented the safety and efficacy of Baycol.<sup>10</sup> Her complaint alleges that Bayer defrauded the government by omitting or downplaying risk and adverse incidents and by implying Baycol was of comparable efficacy to Lipitor. Am. Compl. ¶ 135. Ms. Simpson cannot be the original source of these allegations because she testified that determinations on risk and incidence of adverse events cannot be based on the number of adverse events reported. *See, e.g.,*

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<sup>10</sup> Ms. Simpson repeatedly testified that Baycol had a “proven safety profile” and that Baycol was “safe and effective” when prescribed according to its labeling. *Id.* at 46:6-22, 159:10-24, 168:6-169:18. She now claims that she so testified only because she was told the FDA had approved the medicine as safe and effective. Simpson Decl. at 5. Ms. Simpson never offered this rationalization during her deposition. Instead, she testified that the real problem was that doctors refused to heed Bayer’s repeated warnings and continued to prescribe Baycol in a manner that was expressly contraindicated.” *See, e.g.,* Simpson Dep. (Ex. A) at 381:1-6, 392:3-394:14.

But even if the Court were to accept her tardy and convenient rationalization, that would do nothing to establish Ms. Simpson as an original source regarding allegedly fraudulent misrepresentations regarding the safety of Baycol. *Cf. Russell v. Acme-Evans Co.*, 51 F.3d 64, 67-68 (7th Cir. 1995) (Posner, J.) (“We have been highly critical of efforts to patch up a party’s deposition with his own subsequent affidavit . . . Almost all affidavits submitted in litigation are drafted by the lawyers rather than by affiants. . . Where deposition and affidavit are in conflict, the affidavit is to be disregarded unless it is demonstrable that the statement in the deposition was mistaken . . . .”); *accord Canfield Tires, Inc. v. Michelin Tire Corp.*, 719 F.2d 1361, 1364-65 (8th Cir. 1983).

Simpson Dep. (Ex. A) at 130:10-16, 177:13-178:23; 322:15-324:8.<sup>11</sup> Further, Ms. Simpson testified that she was not aware of complaints to Bayer concerning Baycol's safety. *See, e.g., id.* at 54:2-6, 56:25-57:6, 224:19-226:13, 416:6-418:13. She also denied that Bayer materials misleadingly compared the efficacy of Baycol and Lipitor. *E.g., id.* at 113:6-18, 400:25-401:13.

In sum, Ms. Simpson cannot run from her own deposition testimony, which is properly before the Court and demonstrates that she is not an original source of the allegations in her complaint.<sup>12</sup>

**2. Ms. Simpson cannot establish that she is an original source based on information she “could” have known.**

At bottom, Ms. Simpson's argument is that she can establish jurisdiction simply by asserting that she may be an original source because she “could” have direct and independent knowledge of the facts that form the basis of her complaint by virtue of her work in Baycol market research over a period of time. *Opp.* at 18-19, 22-23. But this is not enough to establish original-source status.

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<sup>11</sup> *See also In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1039-40 (D. Minn. 2007) (excluding expert testimony that purported to make comparative risk findings based on adverse event reports).

<sup>12</sup> Ms. Simpson's deposition further reveals that she lacked knowledge of her “new allegations.” *Opp.* at 13-15. For example, Ms. Simpson alleges that (1) “Bayer specifically designed certain clinical trials to produce potentially misleading and biased results . . .”, *id.* at 14, and (2) “Bayer continued to promote, downplay the risk of, and conduct trials regarding the use of Baycol in combination with certain other drugs, i.e., fenofibrate,” *see id.* However, Ms. Simpson testified that she had no involvement in clinical trials or reporting. *Simpson Dep.* (Ex. A) at 438:24-439:11.

Rather, the law requires that the relator in a *qui tam* action demonstrate that she actually possesses such knowledge. *See* 31 U.S.C. § 3730(e)(4)(B) (original source is “an individual who . . . **has** direct and independent knowledge of the information on which the allegations are based”) (emphasis added); *Rockwell Int’l Corp.*, 549 U.S. at 467-70 (whether putative relator actually “has” direct and independent knowledge of facts underlying claims is a jurisdictional requirement). “Direct knowledge under the Act has been defined as knowledge marked by absence of an intervening agency, or unmediated by anything but [the plaintiff’s] own labor.” *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995) (internal citations and quotations omitted); *Kinney*, 327 F.3d at 674. Independent knowledge is knowledge “not dependent on public disclosure.” *Barth*, 44 F.3d at 703.

Ms. Simpson cannot meet that standard simply by asserting that she was in a position to acquire direct and independent knowledge of some of the facts underlying her claims. Contrary to her assertions, *Minn. Ass’n*, 276 F.3d at 1050, does not hold that she can have direct and independent knowledge of only some facts, and fill the gaps with extraneous materials for which she is not the original source. *Opp.* at 18-22. The Eighth Circuit concluded that an association could be an original source for *qui tam* allegations even though it did not “have personal knowledge of all elements of a cause of action” where its members had personal knowledge of “the true state of the facts.” *Minn. Ass’n*, 276 F.3d at 1050. Here, Ms. Simpson cannot establish that she is an original source for “the true state of the facts.” She (a) has failed to plead any specifics regarding Bayer’s purportedly fraudulent billing practices, *see infra*, Part II, (b) has affirmatively disclaimed



knowledge of the facts underlying her claims, and (c) instead asserts that she was in a position where she could acquire direct and independent knowledge of those facts. That is not enough, even under the most liberal interpretation of *Minnesota Association*.<sup>13</sup>

Ms. Simpson also cites *United States ex rel. Houck v. Folding Carton Admin. Comm.*, No. 87 C 1253, 1988 WL 74829 (N.D. Ill. Jan. 20, 1988), which she says supports the proposition that information gleaned from an ongoing multidistrict litigation can provide the basis for direct knowledge of facts underlying allegations in a *qui tam* action. *See Opp.* at 22. In *Houck*, however, the substance of the *qui tam* allegations related to the payment of claims pursuant to a settlement agreement, and the relator was found to have direct (but not independent) knowledge of the facts underlying the allegations because he assisted claimants in pursuing claims under that settlement agreement. *Houck*, 1988 WL 74829, at \*4. Here, Ms. Simpson is doing nothing more than reciting allegations from complaints and transcripts already in the public record. That does not constitute direct and independent knowledge regarding those allegations.

In sum, Ms. Simpson cannot meet the jurisdictional burden of establishing that she is an original source for her allegations by claiming that she “could” have direct

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<sup>13</sup> Ms. Simpson’s citation to *United States ex rel. Stinson v. Prudential Ins. Co.*, 944 F.2d 1149 (3d Cir. 1991), is similarly unavailing. *See Opp.* at 22. Ms. Simpson claims that *Stinson* stands for the proposition that a putative relator’s investigation can provide the grounds for her to be an original source under the False Claims Act. But *Stinson* requires that the investigation be direct and not rely on any intermediate sources. *See Stinson*, 944 F.2d at 1160-61. Having affirmatively disclaimed knowledge of the facts underlying her allegations, she can assert no more than that she “could” have direct and independent knowledge. But mere possibility cannot establish jurisdiction.

and independent knowledge of the facts underlying those allegations. Her claims should be dismissed accordingly.

## **II. MS. SIMPSON’S CLAIMS MUST BE DISMISSED BECAUSE SHE FAILS TO PLEAD FRAUD WITH PARTICULARITY.**

Even if Ms. Simpson could establish this Court’s jurisdiction – and she cannot – her claims should be dismissed because she has failed to plead fraud with particularity. Specifically, she has brought a case under the False Claims Act without pleading a single false claim or scienter.

### **A. Simpson Fails To Allege Even a Single Representative Example of a False Claim.**

Ms. Simpson asserts that she is not required to plead any actual instances of a false claim to pursue a case under the False Claims Act. Opp. at 31. Rather, she contends that the rest of her complaint – cribbed from public domain documents – is sufficiently specific to provide “circumstantial evidence” that Bayer filed false claims. Opp. at 31. This is simply wrong.

Complaints alleging False Claims Act violations must be pled with particularity in compliance with Rule 9(b). *See Joshi*, 441 F.3d at 556. As in any fraud case, Simpson must specifically describe the details – the “‘who, what, where, when, and how’” – of the alleged False Claims Act violations. *Id.* Critically, she must provide “representative examples” of false claims “specifying the time, place, and content . . . and the identity of the actors.” *Id.* at 557. *Accord United States ex rel. Clausen v. Lab. Corp. of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004); *Yuhasz v. Brush Wellman*,

*Inc.*, 341 F.3d 559, 563-65 (6th Cir. 2003). An abundance of detail about one element of a claim is not a license to omit critical facts about other equally necessary elements. *See Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (dismissing complaint because relator only alleged the “who,” “what,” “where,” “when,” and “how” of “improper practices,” without alleging the details of “fraudulent submissions” to the government). *See generally Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (neither “labels and conclusions” nor “formulaic recitation of the elements of a cause of action” suffice); *Ashcroft v. Iqbal*, \_\_\_ U.S. \_\_\_, 129 S. Ct. 1937, 1954 (2009) (“the Federal Rules do not require courts to credit a complaint’s conclusory statements without reference to its factual context”).

Ms. Simpson relies on a recent Fifth Circuit case, *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009), for the proposition that “particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted” are acceptable for pleading purposes. *Opp.* at 30-31. But even the outlier *Grubbs* court would not accept a False Claims Act complaint with the gaping holes present in Ms. Simpson’s complaint. The *Grubbs* court envisioned a “qui tam plaintiff prov[ing] the existence of a billing scheme and offer[ing] particular and reliable indicia that false bills were actually submitted as a result of the scheme – such as dates that services were fraudulently provided or recorded, by whom, and evidence of the department’s standard billing procedure.” *Grubbs*, 565 F.3d at 189.

Here, however, Ms. Simpson offers no such indicia that false claims were submitted: no submission dates, identities, or standard billing procedures. She objects

that she has, indeed, provided “numerous details” of Bayer’s alleged “misconduct.” Opp. at 30. But this misses the point. Even if Simpson is not required to recite the details of every false claim allegedly made during the three-and-a-half-year period when Baycol was sold, she must provide information as to some claims in the period. “When a qui tam relator pleads a complex and far-reaching fraudulent scheme it must provide examples of specific false claims submitted to the government pursuant to that scheme in order to comply with Rule 9(b).” *United States ex rel. Snapp, Inc. v. Ford Motor Co.*, 532 F.3d 496, 503 (6th Cir. 2008) (internal citation and quotations omitted). *Compare Joshi*, 441 F.3d at 560 (decrying relator’s failure “to plead some representative samples” of allegedly fraudulent claims submitted over a sixteen-year period)<sup>14</sup> *with United States ex rel. Murphy v. Baptist Medcare, Inc.*, No. 4:02-CV-440, 2006 WL 3147440, at \*2 (E.D. Ark. Nov. 1, 2006) (holding that plaintiff met her burden by offering “representative examples” of false claims that “[met] the who, what, where, when, and how” requirements).

Simpson also incorrectly argues that lack of access to details diminishes the need to plead the claims with particularity. Opp. at 32. The Eighth Circuit has explicitly rejected the argument “that the particularity requirements of Rule 9(b) may be relaxed in an FCA qui tam action” because the relator has inferior or unequal access to information.

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<sup>14</sup> Ms. Simpson attempts to distinguish *Joshi* as addressing “only very broad averments and conclusory allegations.” Opp. at 32. In fact, the Eighth Circuit in *Joshi* remarked on the inadequacy of a table in the relator’s proposed amended complaint summarizing the medications given to seven patients identified by initials during six days of a particular month. *Joshi*, 441 F.3d at 555, 558. Even this level of detail was insufficient because the complaint still lacked important details, such as the amount of the claim and the name of the person submitting the claim.

*Joshi*, 441 F.3d at 559. This “reluctance . . . to permit qui tam relators to use discovery to meet the requirements of Rule 9(b) reflects, in part, a concern that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs.” *Id.*

**B. Simpson Fails To Identify Any One Person at Bayer with Knowledge of The Submission of False Claims.**

Similarly, Simpson has failed to plead scienter with the requisite particularity. To plead scienter under the False Claims Act, a relator must allege that the defendant “knowingly submit[ed] or conspire[d] to submit false claims to the government for payment or approval.” *Joshi*, 441 F.3d at 556. Allegations of general corporate knowledge cobbled together from different employees are insufficient; the relator must allege that at least one identifiable person knew of a false claim.<sup>15</sup> *See, e.g., United States v. Sci. Applications Int’l Corp.*, 555 F. Supp. 2d 40, 56 (D.D.C. 2008) (“[T]he issue of material importance . . . [is] whether there was at least one . . . employee who knew or should have known that [the defendant] was submitting a bid seeking government funds and that this bid was tainted”) (internal quotations omitted); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 & n.9 (4th Cir. 2003) (affirming jury instruction that “at least one individual employee [must have] had all of the relevant information to satisfy the standard as to the fact or action at

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<sup>15</sup> Bayer is not disputing, as Ms. Simpson claims, that the knowledge of an employee acting within the scope of his employment is imputed to the employer. *See* Opp. at 33. Nor is Bayer arguing, as Ms. Simpson claims, in favor of the collective knowledge doctrine. *See id.* at 33-34. Both doctrines are irrelevant here, where the only issue is Ms. Simpson’s failure to allege that any one person at Bayer knew of the submission of false claims.

issue”); *United States ex rel. Maxwell v. Kerr-McGee Oil & Gas Corp.*, No. 04-cv-01224, 2009 WL 3161828, at \*5 n.8 (D. Colo. Sept. 30, 2009) (agreeing with the district court that the key issue was “whether there was at least one . . . employee who knew or should have known that [the defendant] was submitting [false claims]”) (internal citation and quotations omitted).

In her complaint, Ms. Simpson alleges that Dr. Ebsworth knew of fraudulent marketing, *see* Am. Compl. ¶¶ 53-55, and that Dr. Plischke ordered the concealment of health risks, *see id.* ¶¶ 94-99. But Ms. Simpson does not allege that any one identifiable person at Bayer actually knew of the submission of a false claim. *See* Opp. at 33. Accordingly, she has failed to plead scienter as required by Rule 9(b), and her False Claims Act claims should be dismissed.

### **III. MS. SIMPSON’S CLAIM UNDER THE ANTI-KICKBACK STATUTE DOES NOT SUPPORT A CLAIM UNDER THE FALSE CLAIMS ACT.**

Ms. Simpson does not respond to Bayer’s argument that her claim under the Anti-Kickback Statute fails because the statute does not provide for a private right of action. *See W. Allis Mem’l Hosp., Inc. v. Bowen*, 852 F.2d 251, 255 (7th Cir. 1988); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 37 (D.D.C. 2003). Instead, she tries to recast her claim as arising under the False Claims Act. But a violation of the Anti-Kickback Statute should not provide the basis for a claim under the False Claims Act. *See, e.g., Thomas*, 2008 WL 4853630, at \*9 (dismissing a False Claims Act claim based on a violation of the Anti-Kickback Statute); *United States ex rel. Woods v. N. Ark. Reg. Med. Ctr.*, No. 03-3086, 2006 WL 2583662, at \*5 (W.D.

Ark. Sept. 7, 2006) (same); *Murphy v. Baptist Health*, No. 4:04-cv-112, 2004 WL 1474655, at \*2 (E.D. Ark. Feb. 23, 2004) (same).

Even if a violation of the Anti-Kickback Statute did give rise to a cause of action under the False Claims Act, that claim should be dismissed for the reasons above. In particular, Ms. Simpson fails the “public disclosure” bar because her kickback allegations, including those she designates as “new” (Opp. at 14-15), are based upon kickback allegations that have long been part of the public record.<sup>16</sup> Thus, at best, Ms. Simpson’s kickback allegations do nothing more than recapitulate kickback claims that have been previously publicly disclosed.

Nor is Ms. Simpson an original source of these claims. She admitted during her deposition that she was not involved in any direct communications with physicians, and Bayer documents that Ms. Simpson authored make clear that she had “nothing to do with” alleged kickback programs, such as CAPS. *See, e.g.*, Simpson Dep. (Ex. A) at 69:8-70:3, 206:17-207:6, 248:1-7, 338:19-339:2, 436:20-437:7, 438:10-23 (disavowing any role in the creation of Baycol’s marketing or any other communications to providers); Email by L. Simpson dated Sept. 16, 2000 (BAYCORP02518643) (Ex. 14); *see also* Am. Compl. ¶¶ 113-33 (CAPS allegations). Because Ms. Simpson’s

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<sup>16</sup> *See, e.g.*, More Locals Jump on Baycol Bandwagon: New Liability Theories Emerge As Lawyers Plot Strategy, THE LEGAL INTELLIGENCER, September 4, 2001(Ex. Y) (“Sheller said he believes discovery will also uncover the existence of illegal bonuses, or ‘kickbacks,’ paid by the defendants in exchange for making the switch to Baycol”); *Haltom v. Bayer Corp.*, No. 02-60165-2, Pre-Trial Motion Record (Ex. K) at 46:11-19 (Nueces County Ct., Tex. Feb. 18, 2003) (“In Texas, it is against the law to peddle your drugs to HMOs by offering rebates and kickbacks and this kind of thing, and we have evidence that they did that . . .”).

Anti-Kickback claims are not cognizable under False Claims Act, they should be dismissed.

**IV. THE STATUTE OF LIMITATIONS BARS THOSE CLAIMS BASED ON PAYMENT CLAIMS SUBMITTED BEFORE OCTOBER 5, 2000.**

Ms. Simpson appears to suggest that, because a small fraction of her case may be timely, the “statute of limitations does not bar this action.” *See* Opp. at 35. She is incorrect. Her action is time-barred as to any claims submitted before October 5, 2000. *United States ex rel. Fisher v. Network Software Assocs., Inc.*, 180 F. Supp. 2d 192, 195 (D.D.C. 2002) (plaintiff may only recover for violations “that occurred after [the limitations date], but not those that occurred before that date”).

**V. MS. SIMPSON’S UNTIMELY CLAIMS UNDER STATE FALSE CLAIMS ACTS ALSO FAIL.**

Ms. Simpson’s claims under state false claims statutes also fail. First, this matter is ripe for a motion to dismiss, and Ms. Simpson should not be permitted to defend such a motion on behalf of states that have not yet decided to intervene. Second, as discussed in Bayer’s opening brief, each state claim is barred entirely or in part by the applicable limitations period.<sup>17</sup> Third, Ms. Simpson has failed to establish subject-matter jurisdiction under the false claims acts of nine states. Five have the same public

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<sup>17</sup> *See also* Del. Code Ann. tit. 6, § 1209; Haw. Rev. Stat. § 661-24; 740 Ill. Comp. Stat. § 175/5(b); Mass. Gen. Laws ch. 12, § 5K(1); Nev. Rev. Stat. § 357.170.1; N.Y. State Fin. Laws § 192(1)(a)-(b); Tenn. Code Ann. § 71-5-184(b)(1); D.C. Code § 2-308.17(a). Moreover, Florida, California, and Louisiana’s shorter statutes of limitations bar Simpson’s claims in their entirety. *See* Defs.’ Br. at 36-38.



disclosure requirements as the False Claims Act<sup>18</sup> and four have narrower original source exceptions.<sup>19</sup> Ms. Simpson has failed to establish jurisdiction under these statutes for the same reasons that she has failed to establish it federally. Moreover, every state claim (except Texas, which did not even provide for a private cause of action at the time Bayer allegedly submitted false claims<sup>20</sup>) should be dismissed because Ms. Simpson fails to satisfy the same heightened pleading requirements required by the Federal Rules. *See supra* Part II; *see also* Defs.' Br. at 35-36.

### CONCLUSION

For the foregoing reasons, the Relator's Amended Complaint should be dismissed with prejudice in its entirety.

DATED: November 13, 2009

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<sup>18</sup> *See* Del. Code Ann. tit. 6, § 1206(c); Fla. Stat. § 68.087; 740 Ill. Comp. Stat. § 175/4(e)(4)(B); La. Rev. Stat. Ann. § 46:439.1(B)(2); Mass. Gen. Laws ch. 12, § 5G(3); N.Y. State Fin. Laws § 190(9)(b); Tenn. Code Ann. § 71-5-183(d)(2)(B); *see also* Defs.' Br. at 34.

<sup>19</sup> *See* Cal. Gov't Code § 12652(d)(3)(B); Haw. Rev. Stat. § 661-28; Nev. Rev. Stat. § 357.100.2; D.C. Code § 2-308.15(c)(2)(B) ; *see also* Def.'s Mot. to Dismiss 36-37.

<sup>20</sup> *See* Defs.' Br. at 36.

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CERTIFICATE OF SERVICE

I, David L. Barlett, certify that true and correct copies of the foregoing  
Reply in Support of Motion to Dismiss, with exhibits, was electronically filed and served  
on November 13, 2009, and that on that same date a copy of Exhibit 14, filed under seal,  
was transmitted by U.S. Mail to

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